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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-----------------|-------------------------|---------------------|------------------|
| 09/774,555 | 01/31/2001 | Mitchell Anthony Delong | 7996 | 4966 |
| 23409 | 7590 05/23/2005 | EXAMINER | | |
| MICHAEL BEST & FRIEDRICH, LLP 100 E WISCONSIN AVENUE | | | BADIO, BARBARA P | |
| | E, WI 53202 | | ART UNIT | PAPER NUMBER |
| | - | | 1617 | |

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|--|--|--|--|--|--|
| | 09/774,555 | DELONG ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Barbara P. Badio, Ph.D. | 1617 | | | | |
| The MAILING DATE of this communication app Period for Reply | pears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL' THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a repl If NO period for reply is specified above, the maximum statutory period or - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be tim y within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONEI | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | _• | | | | | |
| 2a)⊠ This action is FINAL . 2b)□ This | This action is FINAL . 2b) This action is non-final. | | | | | |
| 3) Since this application is in condition for allowa | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | | |
| closed in accordance with the practice under E | Ex parte Quayle, 1935 C.D. 11, 45 | 33 O.G. 213. | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) 1-44 is/are pending in the application 4a) Of the above claim(s) 7.9.10.12 and 22-44 5)□ Claim(s) is/are allowed. 6)⊠ Claim(s) 1-6.8.11 and 13-21 is/are rejected. 7)□ Claim(s) is/are objected to. 8)□ Claim(s) are subject to restriction and/o | is/are withdrawn from considerati | on. | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the Examine 11. | epted or b) objected to by the Education of the Education of the Idea of the I | e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d). | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority document 2. Certified copies of the priority document 3. Copies of the certified copies of the priority application from the International Bureau * See the attached detailed Office action for a list | s have been received. s have been received in Application rity documents have been received (PCT Rule 17.2(a)). | on No ed in this National Stage | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| Notice of Draftsperson's Patent Drawing Review (PTO-948) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date S Point and Todoport Office. | Paper No(s)/Mail Da 5) Notice of Informal Pa | ite atent Application (PTO-152) | | | | |

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Application

2. Claims 1-44 are pending in the present application. Claims 22-44 stand withdrawn without traverse as being drawn to a nonelected invention. Claims 7, 9, 10 and 12 stand withdrawn from further consideration as being drawn to a nonelected species.

Claim Rejections - 35 USC § 112

3. The rejection of claim 15 under 35 USC 112, second paragraph is withdrawn.

Double Patenting

4. The provisional rejection of claims 1-6, 8, 11 and 13-21 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/774,557 is maintained.

Applicant argues the instantly claimed compounds differ from those of the above copending application. Attention is drawn to variable "X" of both applications.

Applicant's argument was considered but not persuasive for the following reason.

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Applicant's argument is based on the definition of variable "X" of each application. However, variable X of claim 1 of the present application corresponds to "O-R₂" of structure aa) of copending application '557 (note: each variable is attached to C15 position of the disclosed structure).

Both applications are drawn to a composition comprising similar prostaglandin F analogs. For example, both encompass compounds wherein C15 is substituted with - OH (i.e., **in the present application**, wherein R^2 is hydrogen and X is OR^8 wherein R^8 is hydrogen and '557, wherein R^2 is hydrogen) and -CH₂O-Z (i.e., **in the present application**, wherein R^3 and R^4 are hydrogen atoms, Y is an oxygen atom and Z is as defined by the present claim 1 and '557, wherein X is $-CH_2O$ - and Z is as defined by claim 1 of the copending application).

For this reason, the provisional rejection of claims 1-6, 8, 11 and 13-21 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/774,557 is maintained.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1-6, 8, 11, 13-17 and 19-21 under 35 USC 102(b) over Wos et al. (WO 99/12895) is maintained.

Applicant argues there are several differences between the general prostaglandin structure of present claim 1 and that of claim 1 of Wos. Applicant also argues the reference fails to anticipate the present application's disclosure of a carrier. Applicant's argument was considered but not persuasive for the following reasons.

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The instant claims are anticipated as stated in the previous Office Action based on the specific compounds discussed by Wos. For example, the reference discloses compositions comprising compounds of examples 20 and 42 (see page 34, Examples B and C). The compounds and compositions exemplified by said examples are encompassed by the instant claims. In addition to the specific carriers exemplified by said examples, Wos discloses numerous carriers such as talc, stearic acid, sesame oil, glycerin, etc. (see for example pages 31-32, Compositions).

Applicant also argues that there are differences in the definitions of variables between the general structure of the present claim 1 and that of claim 1 of Wos. However, the scope of the prior art compounds versus the instantly claimed compounds is irrelevant to the rejection. The claims are anticipated based on the disclosure of specific compounds/compositions that are encompassed by the instant claims.

For these reasons and those given in the previous Office Action, the rejection of claims 1-6, 8, 11, 13-17 and 19-21 under 35 USC 102(b) over Wos et al. (WO 99/12895) is maintained.

Claim Rejections - 35 USC § 103

6. The rejection of claims 1-6, 8, 11 and 13-21 under 35 USC 103(a) over Wos et al. (WO 99/12895) is maintained.

Applicant's argument and the examiner response are as discussed above in #5.

Other Matters

7. It is suggested that the specification be amended to insert reference to the prior application.

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.

Primary Examiner
Art Unit 1617

BB May 18, 2005